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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,060	02/09/2001	C. Neil Kitson	TDIG.P-001	9997

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[REDACTED] EXAMINER

LAMM, MARINA

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1616
DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,060	KITSON ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 November 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
 - 4a) Of the above claim(s) 22-40 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-21 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claims 6 and 15 are objected to because of the following informalities: the use of abbreviations. Appropriate correction is required.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-8 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Elias et al. (US 5,643,899).

Elias et al. teach an aqueous based skin barrier treatment composition containing a combination of cholesterol, ceramide, and fatty acids (e.g. palmitic acid) in the claimed

proportions. See Abstract; col. 5, lines 36-45; col. 21, Example 7. Ceramides can be obtained from bovine brain or other sources. See col. 8, lines 40-65.

With respect to Claims 14 and 19, the presence of surfactants, humectants, solvents and other cosmetic additives is optional. See col. 10, lines 6-11.

With respect to Claims 16 and 17, Elias et al. exemplify compositions that contain neither squalene nor compounds of Claim 17. See col. 21, Example 7.

With respect to Claim 18, Elias et al. exemplify a composition that contains only cholesterol, ceramide and palmitic acid. See col. 17, Table B, Test Series 6.

With respect to the limitation "lipids in a non-crystalline phase lamellar array" in Claim 1, this limitation is inherent in the prior art. It is known that a mixture of the stratum corneum lipids usually forms a lamellar structure (liposomes). See for example, Kawada et al. at col. 2, lines 30-33 or Abraham et al. ("Effects of epidermal acylglucosylceramides and acylceramides on the morphology of liposomes prepared from stratum corneum lipids" at Discussion).

With respect to the limitation "crystalline lamellar phase" in Claims 1 and 8, this limitation is also inherent in the prior art. If the composition of the instant claims adopt a crystalline lamellar phase either upon application to the skin or after the penetration into the stratum corneum, the compositions of Elias et al. will inherently behave the same because they contain the same ingredients as the claimed compositions. Under the doctrine of "inherency", prior art may anticipate a claim if it "inherently" possesses all of the elements of the claimed invention, even if it "did not fully appreciate the uses, purposes, or properties of the product or process' created. General Electric Company v. Hoechst Celanese Corp., 740 F. Supp. 305, 312 (D. Del. 1990).

With respect to Claims 6, 7 and 15, when the combination of lipids is mixed with aqueous phase by shaking the suspension, the liposomes that are formed are inherently multilamellar and have diameters from 100 to 3000 nm. See col. 21, Example 7 and "Concise Encyclopedia Chemistry", p. 599.

Thus, Elias et al. teach each and every limitation of Claims 1-8 and 14-19.

4. Claims 1-3, 6-9 and 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Kawada et al. (US 5,916,578).

Kawada et al. teach skin treatment compositions containing a liquid crystal phase containing a combination of a compound from ceramide family, cholesterol and a fatty acid (e.g. palmitic acid) in the claimed proportions. See col. 1, lines 5-10; col. 15, Compositions 26 and 27. The lipid compositions of Kawada et al. may be mixed with water. See col. 5, lines 9-15; col. 15, Compositions 26 and 27.

With respect to Claims 6, 7 and 15, when the combination of lipids is mixed with aqueous phase by shaking the suspension, the liposomes that are formed are inherently multilamellar and have diameters from 100 to 3000 nm. See col. 21, Example 7 and "Concise Encyclopedia Chemistry", p. 599.

With respect to the limitation "crystalline lamellar phase" in Claims 1 and 8, this limitation is inherent in the prior art. If the composition of the instant claims adopt a crystalline lamellar phase either upon application to the skin or after the penetration into the stratum corneum, the compositions of Kawada et al. will inherently behave the same because they contain the same ingredients as the claimed compositions. Under the doctrine of "inherency", prior art may anticipate a claim if it "inherently" possesses all of the elements of the claimed

invention, even if it "did not fully appreciate the uses, purposes, or properties of the product or process' created. General Electric Company v. Hoechst Celanese Corp., 740 F. Supp. 305, 312 (D. Del. 1990).

With respect to Claims 14, 16, 17, 18, 19 and 21, the compositions 26 and 27 exemplified in col. 15, are free from all listed ingredients.

Thus, Kawada et al. teach each and every limitation of Claims 1-3, 6-9 and 14-21.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9-13, 20 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Elias et al.

Elias et al. applied as above.

The reference is silent with respect to the structure of the non-crystalline phase as claimed in the instant claims. However, since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show novel and unobvious differences between the claimed product and the product of the prior art (i.e., that the lipid compositions of the prior art do not possess the same material and functional characteristics of the claimed lipid compositions).

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawada et al.

Kawada et al. applied as above.

With respect to Claims 4 and 5, Kawada et al. do not teach using bovine brain ceramide or ceramide 2. however, Kawada et al. teach that their composition "is used for a cosmetic or pharmaceutical product, it gives the same effect as a known natural ceramide extracted from bovine brain." See col. 11, lines 64-67.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use bovine brain ceramide or any other ceramide used in cosmetic compositions for compositions of Kawada et al. with a reasonable expectation of deriving the same cosmetic effect as set forth in the reference.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 90/01323 teaches dry skin treatment compositions containing a lipid concentrate blended from a combination of the three naturally-occurring lipid groups found in the stratum corneum.

9. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml
12/28/01

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER